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09/013,871	01/27/1998	ULRICH MARTIN	BOER-1059.1-	3853

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EXAMINER
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GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/06/2004

20

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/013,871

Applicant(s)

MARTIN ET AL.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22,23,27 and 29-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22,23,27 and 29-45 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. The Vacatur and Remand to the Examiner, mailed 9/10/03, by the Board of Patent Appeals and Interferences is acknowledged.

Given the comments by the Board, the preamble of claims 22 and 29 give life and meaning to the manipulative steps of the claims. Therefore, the preamble of claims 22 and 29 defines the patient as one who has suffered a polytraumatic event or a severe polytraumatic event.

2. Claims 22, 23, 27 and 29-45 are pending and under consideration.

Claims 1-21, 24-26 and 28 have been canceled previously.

3. The filing date of the recitation of "from 0.5 hours to 4 hours" in claim 32 appears to be the filing date of PCT/US96/13152, filed 8/13/96, as the previous priority documents provide written description for "from 0.5 hours to 3 hours" and not "from 0.5 hours to 4 hours".

The filing date of the recitation of SEQ ID NOS. in claims 40 and 44 appears to be the filing date of PCT/US96/13152, filed 8/13/96, as the previous priority documents do not provide written description for SEQ ID NOS: 2, 4, 5 and 6.

If applicant desires priority prior to 8/13/96 for these "limitations"; applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

The filing date of claims 22, 23, 27, 29-31, 33-39, 41-43 and 45 appears to be the filing date of USSN 08/578,953, filed 12/27/95.

Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in USSN 08/578,953. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

4. Claims 22, 23, 27 and 29-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 22, 23, 27 and 29-40 are indefinite in the recitation of "prevention of multiorgan failure after a polytraumatic event" (e.g. claim 22) and "treating a patient who has suffered a severe polytraumatic event" (e.g. claim 29) because the metes and bounds of said "polytraumatic event" are ill-defined and ambiguous.

Further, the distinction between a "polytraumatic event" and a "severe polytraumatic event" is not defined.

In addition, the therapeutic endpoints of "prevention of multiorgan failure after a polytraumatic event" (e.g. claim 22) and "treating a patient who has suffered a severe polytraumatic event" (e.g. claim 29) are ill-defined and ambiguous.

Applicant is invited to clarify the metes and bounds of "prevention of multiorgan failure after a polytraumatic event" (e.g. claim 22) and "treating a patient who has suffered a severe polytraumatic event", including the targeted patient populations, the therapeutic endpoints and the difference(s) between a "traumatic event" and a "severe traumatic event".

For example, are the claims limited to the prevention of multiple organ failure and to the considerable reduction of the mortality rate of polytrauma patients, as disclosed on page 5, paragraph 3 and page 9, paragraph 2 of the instant specification ?

For example, are the claimed methods met by treating hemorrhagic shock or multiorgan failure?

B) Claims 41-45 are indefinite in the recitation of "a method for prevention acute organ damage associated with extracorporeal circulation of a patient's blood through a heart-lung machine (e.g. claim 41) because the metes and bounds of the claimed patient populations and therapeutic endpoints are ill-defined and ambiguous.

According to page 4, paragraph 4 of the instant specification, acute organ damage caused by cardiovascular surgery, such as aorta-coronary vein bypass operation or cardiac valve operation, where the blood of the patient circulates extracorporeally through a heart-lung machine.

Applicant is invited to clarify the metes and bounds "a method for prevention acute organ damage associated with extracorporeal circulation of a patient's blood through a heart-lung machine

For example, are the claimed methods are met by treating a patient undergoing cardiovascular surgery or particular types of cardiovascular surgery, given applicant's acknowledgment that acute organ damage caused by cardiovascular surgery, such as aorta-coronary vein bypass operation or cardiac valve operation, where the blood of the patient circulates extracorporeally through a heart-lung machine.

Does applicant's disclosure on page 4 of the instant specification serve to acknowledge that it was well known and standard practice by the ordinary artisan at the time the invention was made that cardiovascular surgery, such as aorta-coronary vein bypass operation or cardiac valve operation is necessarily associated with or obviously associated with the extracorporeal circulation of a patient's blood through a heart-lung machine.

C) The applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 41-45 are rejected under 35 U.S.C. § 102(b) as being anticipated by Co (WO 94/12215) (see entire document) in view of well known and standard practice by the ordinary artisan at the time the invention was made that cardiovascular surgery, such as aorta-coronary vein bypass operation or cardiac valve operation is necessarily associated with the extracorporeal circulation of a patient's blood through a heart-lung machine, as acknowledged on page 4 of the instant specification.

Co teaches the therapeutic and prophylactic use of humanized DREG 55 and DREG 200 antibodies to inhibit disorders or conditions encompassed by the claimed methods (e.g. ischemic events, cardiac surgery, angioplasty; see page 29, paragraph 1 and page 30, paragraph 2)) and dosages which depend on the patient and therapeutic endpoint, including doses of 0.01 - 10 mg and 0.3 - 3 mg/kg, including repeated doses (see entire document, particularly Methods of Use on pages 29-36).

Applicant's disclosure on page 4 of the instant specification serves to acknowledge that it was well known and standard practice by the ordinary artisan at the time the invention was made that cardiovascular surgery, such as aorta-coronary vein bypass operation or cardiac valve operation is necessarily associated with the extracorporeal circulation of a patient's blood through a heart-lung machine. Therefore one of ordinary skill in the art would have immediately envisaged that the teachings of Co of providing intravenously therapeutic amounts of L-selectin-specific antibodies to treat patients having cardiac surgery or angioplasty would have included contacting said patient's blood when it is circulating through a heart-lung machine at the time the invention was made.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations addressed by the applicant would be inherent properties of the referenced methods with L-selectin-specific antibodies.

8. Claims 41-45 are rejected under 35 U.S.C. § 102(a)(b) as being anticipated by Lefer (WO 95/95181) (see entire document) in view of well known and standard practice by the ordinary artisan at the time the invention was made that cardiovascular surgery, such as aorta-coronary vein bypass operation or cardiac valve operation is necessarily associated with the extracorporeal circulation of a patient's blood through a heart-lung machine, as acknowledged on page 4 of the instant specification.

Lefer teaches the therapeutic and prophylactic use of humanized DREG 200 to inhibit a number of disorders or conditions encompassed by the claimed methods (e.g. ischemic events, cardiac surgery and angioplasty) and dosages which depend on the patient and therapeutic endpoint, including doses of 0.01 - 10 mg and 0.3 - 3 mg/kg, including repeated doses (see entire document, particularly Therapeutic Methods on pages 21-26).

Applicant's disclosure on page 4 of the instant specification serves to acknowledge that it was well known and standard practice by the ordinary artisan at the time the invention was made that cardiovascular surgery, such as aorta-coronary vein bypass operation or cardiac valve operation is necessarily associated with the extracorporeal circulation of a patient's blood through a heart-lung machine. Therefore one of ordinary skill in the art would have immediately envisaged that the teachings of Co of providing intravenously therapeutic amounts of L-selectin-specific antibodies to treat patients having cardiac surgery or angioplasty would have included contacting said patient's blood when it is circulating through a heart-lung machine at the time the invention was made.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations addressed by the applicant would be inherent properties of the referenced methods with L-selectin-specific antibodies.

As indicated above, the filing date of the recitation of SEQ ID NOS. in claim 44 appears to be the filing date of PCT/US96/13152, filed 8/13/96, as the previous priority documents do not provide written description for SEQ ID NOS: 2, 4, 5 and 6.

Therefore, Lefer (WO 95/95181) is applied as 102(b) art against claim 44 and as 102(a) art against claims 41-43 and 45.

9. Claims 41-45 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Co (WO 94/12215) AND/OR Lefer (WO 95/1515181) in view of Moat et al. (Ann. Thorac. Surg. 56: 1509 - 1541, 1993) and further in view of Finn et al. (Perfusion 8: 39-48, 1993). in view of well known and standard practice by the ordinary artisan at the time the invention was made that cardiovascular surgery, such as aorta-coronary vein bypass operation or cardiac valve operation is necessarily associated with the extracorporeal circulation of a patient's blood through a heart-lung machine, as acknowledged on page 4 of the instant specification.

The instant claims are drawn to using L-selectin-specific antibodies in the prevention acute organ damage associated with extracorporeal circulation.

Co teaches the therapeutic and prophylactic use of humanized DREG 55 and DREG 200 antibodies to inhibit disorders or conditions encompassed by the claimed methods (e.g. ischemic events, cardiac surgery, angioplasty; see page 29, paragraph 1 and page 30, paragraph 2)) and dosages which depend on the patient and therapeutic endpoint, including doses of 0.01 - 10 mg and 0.3 - 3 mg/kg, including repeated doses (see entire document, particularly Methods of Use on pages 29-36).

Lefer teaches the therapeutic and prophylactic use of humanized DREG 200 to inhibit a number of disorders or conditions encompassed by the claimed methods (e.g. ischemic events, cardiac surgery and angioplasty) and dosages which depend on the patient and therapeutic endpoint, including doses of 0.01 - 10 mg and 0.3 - 3 mg/kg, including repeated doses (see entire document, particularly Therapeutic Methods on pages 21-26).

Co et al. and Lefer et al. differ from the claimed methods by not disclosing the well known and standard practice by the ordinary artisan at the time the invention was made that cardiovascular surgery, such as aorta-coronary vein bypass operation or cardiac valve operation is necessarily associated with the extracorporeal circulation of a patient's blood through a heart-lung machine, as acknowledged on page 4 of the instant specification.

Applicant's disclosure on page 4 of the instant specification serves to acknowledge that it was well known and standard practice by the ordinary artisan at the time the invention was made that cardiovascular surgery, such as aorta-coronary vein bypass operation or cardiac valve operation is necessarily associated with the extracorporeal circulation of a patient's blood through a heart-lung machine. Therefore one of ordinary skill in the art would have immediately envisaged that the teachings of Co of providing intravenously therapeutic amounts of L-selectin-specific antibodies to treat patients having cardiac surgery or angioplasty would have included contacting said patient's blood when it is circulating through a heart-lung machine at the time the invention was made.

In addition, Moat et al. and Finn et al. teach the role of neutrophil adhesion and activation in cardiopulmonary bypass and the importance of blocking said function.

Co and Lefer. differ from the instant claimed methods by not disclosing all of the time points for administering the inhibitory L-selectin antibodies recited in the claims. However, as indicated herein, Co and Lefer do teach dosages encompassed by the claimed methods. Further, it would have been standard practice by the ordinary artisan at the time the invention was made to provide dosages and modes of administration upon the needs of the patient and the nature of the intended therapeutic endpoint. Co and Lefer do teach single and multiple administrations sufficient to cure or at least partially arrest the disease and its complications; which would depend on the severity of the disease and general state of the of the immune system in a patient; which can be administered as bolus or repeated injections to achieve optimal plasma levels of antibody and alone or in combination with other therapeutic agents or drugs (see Methods of Use).

Therefore, the prior art made and used L-selectin antibodies including the DREG 55 and DREG 200 specificities to inhibit inflammation including those associated with neutrophil adhesion and activation and the nature of the injuries claimed in the instant methods. The particular humanized L-selectin antibodies were known in the prior art or could have been made by routine technology at the time the invention was made. Although some of the references are silent about the exact sequences of the L-selectin-specific antibodies, the standard recombinant techniques and computer analyses of CDR known in the prior art would have resulted in the same or very nearly the same structural and functional characteristics of the instant claims since both the references and instant invention use the same techniques, the same antibody specificities and the same goals. For example, see the humanization of antibodies taught by Co and Lefer. Also, such humanization of antibodies for therapeutic uses was well known and practiced at the time the invention was made. The claimed functional limitations encompassed by the claims would be expected properties of selecting for L-selectin-specific antibodies to specifically bind and inhibit L-selectin.



The claims drawn to specifically defined humanized antibodies are obvious since the record does not contain any evidence that the antibodies differ in any significant manner that one of ordinary skill in the art would expect to generate using L-selectin as the starting antigen in the basic method of generating antibodies and humanizing said antibodies.

There appears no evidence that the use of various sources of framework amino acids would differ in an unexpected or distinct manner from those available to the ordinary artisan at the time the invention was made. Also, Co and Lefer appear to teach the same DREG 55/DREG 200 antibodies of the claimed invention.

One of ordinary skill in the art at the time the invention was made would have been motivated to treat patients undergoing various cardiovascular procedures wherein extracorporeal circulation through a heart-lung machine is routinely employed by providing anti-L-selectin antibodies to inhibit neutrophil-mediated inflammatory responses in patients undergoing such cardiovascular procedures. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 22, 23, 27 and 29-40 are rejected under 35 U.S.C. § 103 as being unpatentable over Co (WO 94/12215) in view of Walt et al. (World Journal of Surgery 7: 164-166, 1983).

The instant claims are drawn to using L-selectin-specific antibodies in the treatment of patients who have suffered polytrauma.

Co teaches the therapeutic and prophylactic use of humanized DREG 55 and DREG 200 antibodies to inhibit disorders or conditions encompassed by the claimed methods (e.g. cerebral ischemic event, brain surgery, shock, sepsis, adult respiratory distress syndrome, multiple organ failure as well as injuries due to trauma; see page 29, paragraph 1) and dosages which depend on the patient and therapeutic endpoint, including doses of 0.01 - 10 mg and 0.3 - 3 mg/kg, including repeated doses (see entire document, particularly Methods of Use on pages 29-36).

Co et al. differs from the claimed invention by not disclosing the disorders or conditions such as shock, sepsis and multiple organ failure are resultant of polytrauma.

Walt et al. teach the hemorrhagic shock, cardiopulmonary failure and sepsis are the patients' greatest enemies in the treatment of multiple trauma patients (see entire document, including page 165, column 2, paragraph 2).

Co differs from the instant claimed methods by not disclosing all of the time points for administering the inhibitory L-selectin antibodies recited in the claims. However, as indicated herein, Co does teach dosages encompassed by the claimed methods. Further, it would have been standard practice by the ordinary artisan at the time the invention was made to provide dosages and modes of administration upon the needs of the patient and the nature of the intended therapeutic endpoint. Co does teach single and multiple administrations sufficient to cure or at least partially arrest the disease and its complications; which would depend on the severity of the disease and general state of the of the immune system in a patient; which can be administered as bolus or repeated injections to achieve optimal plasma levels of antibody and alone or in combination with other therapeutic agents or drugs (see Methods of Use).

Therefore, the prior art made and used L-selectin antibodies including the DREG 55 and DREG 200 specificities to inhibit inflammation including those associated with neutrophil adhesion and activation and the nature of the injuries claimed in the instant methods. The particular humanized L-selectin antibodies were known in the prior art or could have been made by routine technology at the time the invention was made. Although some of the references are silent about the exact sequences of the L-selectin-specific antibodies, the standard recombinant techniques and computer analyses of CDR known in the prior art would have resulted in the same or very nearly the same structural and functional characteristics of the instant claims since both the references and instant invention use the same techniques, the same antibody specificities and the same goals. For example, see the humanization of antibodies taught by Co and Lefer. Also, such humanization of antibodies for therapeutic uses was well known and practiced at the time the invention was made. The claimed functional limitations encompassed by the claims would be expected properties of selecting for L-selectin-specific antibodies to specifically bind and inhibit L-selectin.

The claims drawn to specifically defined humanized antibodies are obvious since the record does not contain any evidence that the antibodies differ in any significant manner that one of ordinary skill in the art would expect to generate using L-selectin as the starting antigen in the basic method of generating antibodies and humanizing said antibodies.

There appears no evidence that the use of various sources of framework amino acids would differ in an unexpected or distinct manner from those available to the ordinary artisan at the time the invention was made. Also, Co teaches the same DREG 55/DREG 200 antibodies of the claimed invention.

Given the teachings of Co directed to the therapeutic and prophylactic use of humanized DREG 55 and DREG 200 antibodies to inhibit disorders or conditions encompassed by the claimed methods (e.g. cerebral ischemic event, brain surgery, shock, sepsis, adult respiratory distress syndrome, multiple organ failure as well as injuries dues to trauma; see page 29, paragraph 1 and page 30, paragraph 2), one of ordinary skill in the art would have targeted the same conditions in patients undergoing polytrauma, as shock, cardiopulmonary failure and sepsis are the patients' greatest enemies in the treatment of multiple trauma patients, as taught by Walt et al. (see entire document, including page 165, column 2, paragraph 2). Note, too, that Co et al. does teach treating patients with injuries due to trauma (see page 29, paragraph 1).

One of ordinary skill in the art at the time the invention was made would have been motivated to treat patients undergoing various cardiovascular procedures wherein extracorporeal circulation through a heart-lung machine is routinely employed by providing anti-L-selectin antibodies to inhibit neutrophil-mediated inflammatory responses in patients undergoing such cardiovascular procedures. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 22, 23, 27 and 29-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending application USSN 09/917,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are drawn to the same or essentially the same methods of targeting patients after a polytraumatic event.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
February 5, 2004